



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,836	03/15/2002	Jean-Louis Dasseux	9196-0022-999	5585
20583	7590	06/23/2004	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			CELSA, BENNETT M	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 06/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/099,836

Applicant(s)

DASSEUX ET AL.

Examiner

Bennett Celsa

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-18,20-27,29,34,35,37,42,44 and 54-56 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1,3-18,20-27,29,34-35,37,42,44 and 54-56 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION: *Election/Restriction*

Status of the Claims

Claims 1, 3-18, 20-27, 29, 34-35, 37, 42, 44 and 54-56 are currently pending.

I. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 (in part), 3-9, 12-18 (in part), 29 (in part), 34 (in part), 35(in part), 37(in part) and 42 (in part) drawn to a peptide comprising X1-X23 of formula I and conservative substitutions thereof, a lipid complex and pharmaceutical thereof, classified, for example, in class 530, subclass 324-325.
- II. Claims 1 (in part), 10-11, 12-18 (in part) and 29 (in part), 34 (in part), 35(in part), 37 (in part) and 42 (in part) drawn to a deletion analog (e.g. 1-8 amino acids deleted of X1-X22 in any order) of formula I and a lipid complex and pharmaceutical thereof, classified, for example, in class 530, subclass 326.
- III. Claims 20, 23-27(in part) and 29 (in part), 34 (in part), 35(in part), 37 (in part) and 42 (in part) drawn to a multimeric ApoA-I agonist of formula II and a lipid complex thereof, classified in different classes/subclasses (e.g. 514 and 530) to be determined upon election of species.
- IV. Claims 21, 23-27(in part) and 29 (in part), 34 (in part), 35(in part), 37 (in part) and 42 (in part) drawn to a multimeric ApoA-I agonist of formula III, classified in different classes/subclasses (e.g. 514 and 530) to be determined upon election of species.
- V. Claims 22, 23-27(in part) and 29 (in part), 34 (in part), 35(in part), 37 (in part) and 42 (in part) drawn to a multimeric ApoA-I agonist of formula IV or V and a lipid complex thereof, classified in different classes/subclasses (e.g. 514 and 530) to be determined upon election of species.
- VI. Claims 44 and 55-56 (in part) drawn to a method of treating dyslipidemia, classified in class 514, subclass 2+.
- VII. Claims 54 and 55-56 (in part) drawn to a method of treating shock, classified in class 514, subclass 2+.

Art Unit: 1639

II. The inventions are distinct, each from the other because of the following reasons:

III. Inventions I-II are drawn to patentably distinct species of peptides of different amino acid composition and length so as to result in peptides with different physicochemical properties which are capable of separate manufacture and/or use and which necessitate separately burdensome manual/computer sequence, structure, name and/or bibliographic searches

IV. Inventions III-V are drawn to patentably distinct species of multimeric ApoA-I agonist peptides of different amino acid composition and length so as to result in peptides with different physicochemical properties which are capable of separate manufacture and/or use and which necessitate separately burdensome manual/computer sequence, structure, name and/or bibliographic searches.

V. The compounds of Inventions I-II as compared to Inventions III-V are drawn to patentably distinct species of peptides of different amino acid composition and length so as to result in peptides with different physicochemical properties which are capable of separate manufacture and/or use and which necessitate separately burdensome manual/computer sequence, structure, name and/or bibliographic searches

VI The methods of Inventions VI and VII are drawn to patentably distinct treatment methods due to differences in method objectives, patient treatment and additionally involve a different and separately burdensome manual and/or computer bibliographic search in patent/literature databases.

VII Inventions (I or II or III or IV or V) and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product e.g. products of

Art Unit: 1639

Groups I-V are alternative products to be used in method of Group VI; and the product as claimed can be used in a materially different process of using that product such as to treat septic shock.

VIII Inventions (I or II or III or IV or V) and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product e.g. products of Groups I-V are alternative products to be used in method of Group VI; and the product as claimed can be used in a materially different process of using that product such as to dyslipidemia.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper

Upon election of any single one of the Groups I-VII above the following election of species is required:

RESTRICTION/ELECTION OF SPECIES (For Groups I-VII

ABOVE)

The compounds within the claims of Groups I-VII are individually or dependently directed to a plurality of disclosed patentably distinct species of peptides of different amino acid composition and length so as to result in peptides with different physicochemical properties which are capable of separate manufacture and/or use and which necessitate separately burdensome manual/computer sequence, structure, name and/or bibliographic searches.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species e.g. a single peptide compound, which can be chosen from the specification, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

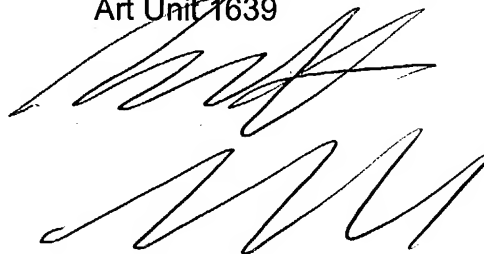
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 571-272-0807. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-273-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bennett Celsa
Primary Examiner
Art Unit 1639



BC
June 16, 2004